May 20, 2004

Richard Balcomb
Head, Toxicology and Environmental Assessments
Ciba Specialty Chemicals Corporation
540 White Plains Road
Tarrytown, New York 10591

Dear Mr. Balcomb:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for IRGANOX MD 1024 posted on the ChemRTK HPV Challenge Program Web site on January 14, 2004. I commend Ciba Specialty Chemicals Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Ciba Specialty Chemicals Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
IRGANOX MD 1024

Summary of EPA Comments

The sponsor, Ciba Specialty Chemicals Corporation, submitted a test plan and robust summaries to EPA for IRGANOX MD 1024 [1,2-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamoyl)hydrazine, CAS No. 32687-78-8] dated December 15, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 14, 2004.

EPA has reviewed this submission and reached the following conclusions:

1. Physicochemical Properties. The data are adequate for the purposes of the HPV Challenge Program; however, the submitter needs to indicate whether the melting point value is measured or calculated.

2. Environmental Fate. The data are adequate for the purposes of the HPV Challenge Program.

3. Health Effects. The data are adequate for the purposes of the HPV Challenge Program, but the submitter needs to address deficiencies in the robust summaries.

4. Ecological Effects. The data for fish, invertebrates, and algae are inadequate for the purposes of the HPV Challenge Program because the tests were conducted above the chemical's water solubility limit. EPA recommends that invertebrate and algal toxicity tests be performed according to OECD TG's 202 and 201, respectively.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the IRGANOX MD 1024 Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data for boiling point, vapor pressure, partition coefficient, and water solubility are adequate for the purposes of the HPV Challenge Program.

Melting Point. The submitter needs to indicate whether the melting point value is measured or calculated. If calculated, the submitter needs to provide a measured value in accordance with OECD TG 102.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data for photodegradation, stability in water, biodegradation, and fugacity are adequate for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Developmental toxicity. In the summary table, the submitter needs to indicate that a NOAEL was not achieved.

Ecological Effects (fish, invertebrates, and algae).

Fish, Invertebrates, and Algae. The submitted test data are inadequate because all tests were conducted above the water solubility limit of the chemical. Because of this factor and the chemical's high Log K_{ow} of 7.9, a chronic daphnid test (OECD TG 202) and an algal toxicity test (OECD TG 201) are recommended.

Specific Comments on the Robust Summaries

Health Effects

General. The submitter needs to indicate the purity of the test substance.

Acute toxicity. The summary for the rat oral study does not identify the guideline followed, the duration of the observation period, the sex of the animals, and body weight changes, if any. In the summary for the Chinese hamster oral study, only one test dose was listed, but the results section states that "20% of deaths were recorded in higher dose group." This discrepancy needs to be clarified.

Developmental toxicity. The fact that a NOAEL was not achieved needs to be indicated in the conclusions.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.